

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

DOUGLAS J. HORN and CINDY HARP-HORN,

Plaintiff,

**AFFIDAVIT OF
KENNETH D. GRAHAM, Ph.D.**

-vs-

Case No. 15-cv-701 FPG/MJR

MEDICAL MARIJUANA, INC.,
DIXIE HOLDINGS, LLC a/k/a DIXIE ELIXERS
RED DICE HOLDINGS, LLC, and
DIXIE BOTANICALS,

Defendants,

I, Kenneth D. Graham, Ph.D., declare the following, pursuant to 28 USC §1746, under penalty of perjury:

1. I am a Forensic Toxicologist with over 25 years of experience in the field. I was retained on behalf of the Plaintiffs to evaluate the evidence and testimony involving the tetrahydrocannabinol (THC) content of the Dixie X Elixir Tincture product taken by Plaintiff, and whether the product complies with federal statutes for controlled substances. As such, I am fully familiar with the facts and circumstances set forth in this affidavit.

2. I make and submit this affidavit in response to plaintiff's motion pursuant to Fed. R. Civ. P. 60(b) for relief from the Decision and Order of Court dated November 22, 2019 to the extent the Court dismissed the Plaintiff's claim under RICO that the Dixie X product at issue was a controlled substance.

3. On November 22, 2019, the Court issued a Decision and Order with respect to various motions between the parties, which granted in part and denied in part MMI/RDH's motion for reconsideration [97] [106] and denied Plaintiffs' cross-motion for reconsideration [112]. In addition, the Court modified its prior order to

preclude Plaintiff from pursuing his claim on the theory that Dixie X is a controlled substance.

4. As background to the Decision and Order, the Court cited two cases, *Hemp Indus. Ass'n v. Drug Enforcement Admin.*, 333 F.3d 1082, 1085 (9th Cir. 2003) and *Hemp Indus. Ass'n v. Drug Enforcement Admin.*, 357 F.3d 1012 (9th Cir. 2004) as the legal basis for denying Plaintiffs' claim that Dixie X is a controlled substance.

5. These two 9th circuit cases dealt with an Administrative Procedures Act issue related to whether enough procedural notification had been provided by the Defendants for enforcement of statutes against the Plaintiffs'. Application of the Administrative Procedures Act is not an element of this case. In addition, the Plaintiffs in these 9th circuit cases were using the hemp plant material and oil as a cosmetic constituent and potential food source (it is unclear whether the material for food was intended for human consumption or as animal feed). In this case, the Dixie X product was based on extracted hemp plant material, formulated and marketed as a "wellness" product, essentially a pseudo-drug product, for the expressed intention of human consumption.

6. The 9th circuit erred in its interpretation that the prohibition against THC referred to synthetic, not naturally occurring THC. The definition of tetrahydrocannabinols under schedule I clearly states tetrahydrocannabinols *naturally contained* in a plant of the genus Cannabis (cannabis plant), *as well as*, synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant, and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those

substances contained in the plant unless specifically excepted. *See* 21 U.S.C. §1308.11.(d) (31). Further, the definition of a hallucinogenic substance under the schedule is any material, compound, mixture or preparation which contains *any* quantity of the hallucinogenic substance. The term “any” is clear and unambiguous and without exceptions for “trace” amounts or “non psychoactive” amounts. *See* 21 U.S.C. §1308.11.(d).

Undisputed by the defendant’s Certificates of Analysis , the product contained an amount of THC.

7. The 9th circuit also erroneously held that products made from exempted parts of the *Cannabis sativa* plant were not included in the definition of marijuana and therefore were not unlawful under the CSA, even if they contained trace amounts of [naturally occurring] THC. In this case, the Dixie X products were unlawful under the CSA because they were made for human consumption which rendered the *Cannabis sativa* plant materials ineligible for the exemption.

8. Without factoring the aspect of human consumption into the determination of exemption eligibility, the Court would respectfully be creating a new loophole by which any amount of THC, including psychoactive concentrations, in a product would be considered lawful if it was derived from hemp plant materials. Clearly, disallowing human consumption of schedule I controlled substances, unless the drug product has been approved as safe and efficacious by the FDA, is necessary to conform with the CSA and protect the public welfare within the meaning of the act. *See* 21 U.S.C. §801(2).

9. The exemption for THC-containing hemp materials as defined under 21 U.S.C. § 802(16) is an acknowledgment that, without such an exemption, a wide variety of industrial products, e.g., paper, rope, clothing, solvents, lubricants, bird seed, cosmetics, derived from the cannabis plant would be considered schedule I controlled substances, which would significantly restrict the use of these products.

10. This exemption for a product made from any portion of a plant of the genus Cannabis excluded from the definition of marijuana under the CSA *does not apply* to a product intended for human consumption such that it is ingested orally or applied by any means such that THC enters the body. *See* 21 U.S.C. §1308.35. THC clearly entered Plaintiff's body from his positive test in a urine drug screen.

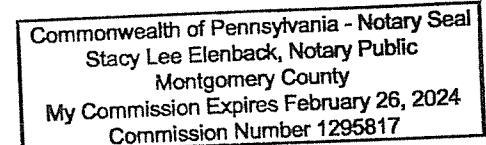
11. Also, under 21 U.S.C. §1308.35 (4), the Dixie X product was not eligible for an exemption as a product made from any portion of a plant of the genus Cannabis excluded from the definition of marijuana under the CSA because it was designed, marketed and distributed as intended to be used for human consumption.

12. Upon information and belief, the Dixie X product that plaintiff purchased and allegedly consumed in 2012 is a controlled substance under the CSA since it was derived from *Cannabis sativa* plant material that was not eligible for an exemption because the final product contained a measurable quantity of THC and was intended for human consumption.

13. The purpose of this Affidavit is to highlight to the Court that it respectfully should not have viewed the 9th Circuit *Hemp I and II* cases as persuasive authority to this situation, or that Plaintiff's case ran afoul of them. To allow the trial to go forward by denying the Plaintiff the opportunity to present to the jury the Defendants' violation of the Controlled Substances Act would respectfully be erroneous.

Dated: August 28, 2020


KENNETH D. GRAHAM, Ph.D.




8/27/2020